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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,282	12/15/2003	Hiroaki Kisaka	245710US0CONT	9578
22850	7590	08/23/2006	EXAMINER	
C. IRVIN MCCLELLAND				ZHENG, LI
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.				
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ALEXANDRIA, VA 22314				
		ART UNIT		PAPER NUMBER
		1638		

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,282	KISAKA ET AL.	
	Examiner Li Zheng	Art Unit 1638	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 January 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/15/03 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3152004/12152003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Specification

1. Specification is objected under 37 CFR 1.821(d) as failing to refer to a sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the specification. The nucleotide sequence in upper line of Figures 1 and 2 is not found in Sequence Listing. Applicant needs to assign the sequence identifiers to those sequences and submit a substitute paper copy of the "Sequence Listing", a copy of the "Sequence Listing" in computer readable form, as well as a statement that the content of the paper and computer readable copies are the same. See the attached Notice to Comply.

Claim Objections

2. Claims 11, 12, 14, 15, 20 and 21 are objected. In instant claims, the references used for comparison should be either the amino acid content or total weight of tuber parts of untransformed plants, not the untransformed plants themselves. Further, in claims 14, 15, 20 and 21, the recitation, "an", should be used preceding the word "untransformed".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, 11 and 12 : the recitation, "edible parts", render the claims indefinite. It is not clear what part of a plant belongs to "edible parts" without information on which plant it is and who is the consumer. The metes and bounds are therefore unclear. For examination purpose, it is interpreted as any part of a plant.

Further, in claims 1, 10, 13 and 20, the recitation, "excessive" or "excessively", renders the claims indefinite. The recitation is a relative term with no definite meaning. The specification does not provide a standard for ascertaining the requisite degree, therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds are not clear.

Still further, in claims 1 and 20, the recitation, "a marker gene connected to the genetic vector", renders the claims indefinite. It is unclear how to connect the construct

with a marker gene. The metes and bounds are unclear. It is suggested to replace the recitation with --in the genetic construct--.

In claims 2, 16 and 20: the recitation, "powerful", renders the claims indefinite. It is a relative term with no definite meaning. The specification does not provide a standard for ascertaining the requisite degree, therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds are not clear. It is suggested to remove the term.

In claim 14, the recitation, "statistically significant increase", render the claim indefinite. It is unclear what statistical measurement is used and what the cutoff is. It is suggested to remove the recitation, "statistically significant".

In claims 11 and 12: the recitation, "progeny", renders the claims indefinite. It is unclear if the progeny comprises the genetic construct. It is suggested to add --,wherein said progeny plant comprises said genetic construct--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6-7, 10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Lightfoot et al. (U.S. Patent No. 5,998,700).

Lightfoot et al. teach that a construct containing *E.coli* gdhA driven by strong constitutive promoter, CaMV 35S promoter (Figure 4), was transformed into tobacco plant. Alanine, lysine and threonine contents were significantly increased by gdhA (column 20, first paragraph). Lightfoot et al. also teach that transgenic corn plants expressing gdhA were also produced. Glutamic acid was increased in transgenic line LL8-67 (Table 6I), compared to that of untransformed corn plant. Seeds of the transgenic plants are also taught. Therefore, the reference therefore teaches all the limitation set forth by instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8, 9, 14, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lightfoot et al. (U.S. Patent No. 5,998,700) in view of de Castro Silva Filho et al. (1996, *Plant Mol. Biol.* 30:769-780) and An et al. (1986, *Plant Physiol.* 81:301-305).

The teachings of Lightfoot et al. are discussed as above. In addition, Lightfoot et al. also teach gdhA fused with transit peptide for chloroplast (Example III, columns 11-12).

Lightfoot do not teach transgenic potato expressing GDH gene and exhibiting an increase in total weight of tuber parts of potato and transit peptide for mitochondria and transgenic tomato.

de Castro Silva Filho et al. teach the sequence encodes for the presequence of the mitochondrial F1-ATPase beta-subunit which alone was able to direct transport of CAT gene to mitochondria (abstract). The presequence herein is equivalent to transit peptide in the instant claims.

An et al. teach a method to produce transgenic tomato and potato (page 301-304).

It would have been obvious for a person with ordinary skill in the art to modify the construct of Lightfoot et al. and result in a construct containing gdhA fused with transit peptide for mitochondria of de Castro Silva Filho et al. under the control of CaMV 35S promoter to transform potato or tomato plants using the method of An et al. The increase of total weight of tuber parts is inherent property in those transgenic potato plants. One would have been motivated to use fuse transit peptide to GDH gene given the teaching of Lightfoot et al. that GDH is expressed in mitochondria (column 1, lines 21-27). One would also have been motivated to transform the modified constructs to potato or tomato given the teaching of Lightfoot et al. that gdhA can be used to increase starch content of crops such as corn, potato and tomato (column 29, lines 18-20).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-26 of U.S. Patent No. 6,969,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims fully anticipate instant claims 1-19. The patented claims teach that a method to produce a potato containing free glutamic acid in a tuber thereof which is at least twice that of the corresponding untransformed potato by transforming a potato with constructs containing a gene encoding GDH from *A. nidulans* having a transit peptide to mitochondria under the control of the CaMV 35S promoter, such as pMt-dAN-gdh. Although the patented claims do not teach the total weight of tuber parts of the transgenic potato exhibit significant increase or 1.5 fold higher compared to that of an untransformed potato cultured under the same conditions, such property is inherent to the transgenic potato expressing the same constructs. The patented claims also teach constructs, such as pT-gdh-4, containing the gene encoding tomato GDH gene having a

transit peptide to mitochondria. Therefore, the patented claims meet all the limitation of instant claims.

Conclusion

Claims 1-25 are rejected. Claims 4, 5, 11, 12, 15, 18 and 20-25 are deemed free of prior art due to the failure of the prior art to teach or fairly suggest using GDH gene from *A. nidulans* or GDH gene tomato fused with transit peptide for mitochondria to transform plant, or a transgenic plant expressing GDH having increase glutamic acid content by at least 2-fold, or a method comprising screening for transgenic potato overexpressing GDH having increased total weight of tuber parts.

Claims 1, 4, 5, 11, 12, 14, 15, 18, 20, 21 and 24 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ASHWIN D. MEHTA, R.S.
PRIMARY EXAMINER